SECTION 2 - 510(K) SUMMARY

OCT 2 4 2002

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
90 Icon St.
Foothill Ranch, Ca 92610
Phone: (949) 580-1555
Fax: (949) 580-1550

The device has been classified as Class III by the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025 "Monitor, Physiological, Patient (with arrhythmia detection or alarms)" per MHX.

The predicate-marketed device is Nihon Kohden CNS-9300 series per 510(K) # K001433, cleared in November 2000.

Common names for the device include Central Nurse Station, Central Monitoring Station and Telemetry Monitoring Station.

The device is intended for use by medical professionals to provide cardiac and vital signs monitoring for multiple patients, up to 16, within a medical facility. The device will display and record physiological data from individual bedside monitors and telemetry receiver/transmitters and generate an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected. Arrhythmia detection and alarm determination are functions of the individual bedside or telemetry channel.

To date, no special controls or performance standards are known or established for this device.

The device is not sterile.

The device is not contacting patients. Therefore, no good laboratory practice studies were required per 21 CFR 58.

The device was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the related functions of acquiring, displaying and recording of all functions of the device. The results confirmed that the device performed within specifications.

Nihon Kohden believes that the CNS-9700 series Central Nurse Stations are substantially equivalent to the Nihon Kohden CNS-9300 series Central Stations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2002

Nihon Kohden America, Inc.
c/o Mr. Serrah Namini
Regulatory Affairs
90 Icon Street
Foothill Ranch, CA 92610

Re: K023475
Trade Name: CNS-9700 Series Central Nurse Station
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Monitoring System
Regulatory Class: Class III (three)
Product Code: MHX
Dated: October 15, 2002
Received: October 16, 2002

Dear Ms. Namini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K023475

Device Name: CNS-9700 series Central Nurse Station

Indications for Use:

The CNS-9700 Series Nurse Central Station is intended for cardiac and vital signs monitoring for multiple patients. The device will display and record physiological data from individual bedside monitors and /or telemetry receiver/transmitters and mimics an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected by the bedside monitor or telemetry unit.

This product will be available for use by medical personnel on all patient populations within a medical facility.

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K023475